EXHIBIT

“F”

IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

IN RE: ETHICON, INC. PELVIC SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: ***Anna Thompson-Key v. Ethicon, Inc., et al.*** ***2:12-cv-06179***	**HON. ROBERT C. CHAMBERS**

RULE 26 EXPERT REPORT OF DR. WILLIAM PORTER, M.D.

A. Qualifications and Background.

My name is William Edward Porter, M.D. I received a bachelor's degree in biology at the University of Michigan located in Ann Arbor, MI. I then went on and obtained a medical degree from the Wayne State University located in Detroit, MI. I subsequently completed a residency in obstetrics and gynecology at the University of Cincinnati and an American Board of Obstetrics and Gynecology certified three-year fellowship in Female Pelvic Medicine and Reconstructive Surgery (FPMRS) at the University of Tennessee Medical Center located in Memphis, Tennessee. I am one of the first ABOG Certified Physicians in the United States in the Field of (FPMRS). I served as a reviewer for the International Urogynecology Journal (2003 to 2006). I am currently a journal reviewer for Female Pelvic Medicine & Reconstructive Surgery. I serve on the American Urogynecology Society Coding Committee (2012 to 2016). I have lectured locally, nationally, and internationally on many subjects in the field of urogynecology and reconstructive pelvic surgery, including pelvic organ prolapse and urinary incontinence. I have taught at many medical device industry sponsored labs, the purpose of which has been to instruct other surgeons on the proper use of surgical devices and tools to treat pelvic organ prolapse and stress incontinence. I have also worked as a consultant to many medical device companies in developing and validating new products in the pelvic floor space.

I am trained extensively and practice exclusively in the field of pelvic medicine. This field encompasses pelvic organ prolapse, urinary incontinence, fecal incontinence, pelvic pain and

pelvic floor dysfunction. Over the past 14 years post residency, I have performed nearly 3,000 pubovaginal slings (synthetic and xenographic) and fascia latta bladder neck slings. I have performed several thousand vaginal repairs for pelvic organ prolapse using native tissue, allograph, xenograph or synthetic augmented repairs. In the same regard I have also removed slings and mesh complicated surgeries (erosion and/ extrusion).

I have been specifically trained to use pelvic organ products (slings, graphs and mesh kits) by the following companies: C. R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare, American Medical System and Coloplast. I did complete any training required by said companies. I have been a trained proctor for the following companies: C.R. Bard, Boston Scientific, Mentor, Cook Medical, Gynecare and Coloplast. I have specifically treated female patients with the TVT and TVT-O mid-urethral slings.

Based upon my work as a urogynecologist (FPMRS), I am familiar with the medical complications that are generally associated with mesh repair surgery, and I am experienced in the recognition, diagnosis and treatment of patients suffering from complications caused by pelvic repair mesh implants and mid-urethral slings. The focus of my evaluation is the role that the TVT and TVT-O played in causing injury to Ms. Thompson-Key. The most common mesh-related complications are pelvic pain, scarring in the vagina and pelvic floor, pain into the legs and thighs, dyspareunia, chronic inflammation of tissue, chronic vaginal discharge or bleeding, scar bands or scar plates in the vagina, vaginal shortening or stenosis, erosion of mesh into tissues or organs, and nerve entrapment. In diagnosing and treating patients with mesh related complications, I often determine the likely cause of the patient's complications based upon a differential diagnosis, which typically includes a physical and history and a review of her medical records and other information about the patient.

In formulating the opinions set forth in this report I have relied on my personal knowledge, education and training, prior experience in treating stress urinary incontinence, medical literature, and a review of relevant medical records pertaining to Ms. Thompson-Key. All of my opinions are true and correct to the best of my knowledge. I do reserve the right to supplement this report and my opinions if additional information becomes available (reports, discovery, articles or other relevant information). I also reserve the right to perform a physical examination on Ms. Thompson-Key.

B. Summary of Materials Reviewed

I have reviewed the following medical records and depositions with accompanying exhibits pertaining to Anna Thompson-Key:

Amanda O'Brien, M.D.

Barnes Jewish Hospital

Carlinville Area Hospital

Chiarra Ghetti, MD

Litchfield Family Practice

Memorial Medical Center

SIU School of Medicine and Healthcare Department of Obstetrics and Gynecology

St. Francis Hospital HSHS St. Francis Hospital

Springfield Clinic

Deposition of Anna Thompson-Key

Plaintiff Profile Form and Plaintiff Fact Sheet of Anna Thompson-Key

C. Summary of Medical Facts related to Anna Thompson-Key

DOB: 11/3/1982

Past Medical History:

Depression

Past Surgical History:

TVT-O, TVT, Sling Revision

Social:

Tobacco ++

7/19/2005

She had a TVT-O.

11/8/2005

Exploration and incision of TVT-O. TVT-O was exposed in the midline. Pathology: Gray-dark brown soft tissue with embedded blue synthetic material.

1/27/2006

She originally had a TVT-O, but the incision broke down in the midline. She had a revision and the excess mesh was trimmed. She underwent a TVT.

4/7/2006

She reports she is wearing pads, but tampons are too painful.

5/21/2007

She had an erosion of TVT into urethra. She had cystoscopy and the mesh was going across the urethra and the distal portion of the urethra. Endo-shears were used to cut the mesh in the middle. Alligator grasping forceps grabbed the mesh and pulled and the mesh was cut flush with the urethra.

6/25/2014

Urethro vaginal fistula surgery: She reports a constant pressure. She feels urgency and frequency and UI. Pathology: fibrosis and chronic inflammation. She feels the fistula could have been the result of electrocautery at time of excision of her urethral mesh erosion and compounded by her smoking. A 2 cm segment of the sling mesh was then dissected off of the urethra. The fibers were in the periurethral tunnel and not accessible. Stray fibers were removed.

7/7/2014

Voiding cystourethrogram

8/4/2014

She was 6 weeks' post-operative from a vaginal excision of mesh, repair of urethrovaginal fistula. She feels that she does not empty her bladder. She denies any dyspareunia. She reports that something is scratching her. She was scheduled for PT.

D. Methodology and Analysis.

In determining the cause of a specific injury, it is customary to "rule in" potential causes of the injury, and then by process of elimination, to "rule out" the least likely causes to arrive at the most likely cause. This process is known as differential diagnosis, or differential etiology, and it is a well-established and universally accepted methodology for determining the cause of injuries employed by physicians throughout the United States. I often determine the cause of a patient's complications based upon an interview with the patient, a review of her medical records or knowledge of her prior medical history. I have used that methodology in arriving at my opinions in the case.

During her visits she reports having pain when using tampons.. Meyer et al reports dyspareunia rates of 36% at a 5 year follow up from mesh surgery. On the other hand, Alperin et al reports a dyspareunia rate of 28.9%, which was similar to preoperative rate. Porter et al reports a site-specific posterior repair tends to have a positive effect on dyspareunia 73% cured vs. 19% where it increased.

As the vagina is a cleaned contaminated area, there is no way to completely eliminate bacteria from the surgical site. Implantation though this dirty field could allow bacteria to attach. These bacteria then can attach to the mesh and secrete a biofilm or a polysaccharide slime excreted by the bacteria. This slime could prevent the host defensive mechanism from clearing the infection. (Edmiston). This tissue response can contribute to the cause of vaginal pain, pelvic pain and chronic inflammation. This chronic inflammation/infection could be a source of pain. This chronic inflammation/infection could be a source of an erosion, vaginal discharge and possible UTI's. Dr. Daniel Elliott in his general expert report suggested the mesh creates a foreign body reaction and a chronic inflammatory response that can lead to chronic pain in the patient. The body's foreign body response to the mesh can cause a severe and chronic inflammatory reaction leading to excessive scarring in and around the mesh. Dr. Bruce Rosenzweig of the general expert witness group suggests that mesh degrades over time and causes a chronic foreign body reaction, fibrotic bridging, mesh contracture/shrinkage, fraying, particle loss, roping and curling of the mesh contributing to pain. Ethicon's Daniel Burkley, a Principal Scientist has testified that polypropylene mesh in human beings is subject to some degree of surface degradation

In considering the cause of the vaginal pain and dyspareunia suffered by Anna Thompson-Key, her TVT sling contributed to her mesh erosion, pain and vaginal scarring. Initially her TVT eroded into the urethra. This is a rare complication. As the sling contracted this caused the erosion of the sling into the urethra. Her physician excised most of the sling from the urethra by cutting it cystoscopically and resecting it from the outside. The residual mesh after the excision caused a chronic inflammation similar to Dr Rosenzweig's description. This chronic inflammation resulted in a second occurrence of erosion of her TVT sling. Her smoking history and electrocautery may have increased the probability of the erosion, but the main cause is the TVT mesh.

The next step in my analysis was to rule out other potential causes. I did consider other potential causes including post-op scarring and granulation tissue from her C-section, hysterectomy and previous bladder neck surgery. I also considered other factors in her medical history. I did consider her medical problems: smoking, depression, history of chlamydia, HPV positive. I considered each of these other risks for her pain, mesh erosion and dyspareunia and I concluded that they could be ruled out as a source of her vaginal pain, mesh erosion and dyspareunia suffered by Anna Thompson-Key.

Additionally, it is my opinion to a reasonable degree of medical and scientific certainty, based on my background, education, training and experience, that Anna Thompson-Key's treating physicians who implanted met the standard of care during implantation of the device. I found no evidence of surgical error or deviation from the requisite procedural steps. Further, after reviewing the operative reports, I see no evidence of any surgical complications.

E. Conclusion.

Based on the foregoing analysis, and based on my education, training and knowledge, it is my opinion to a reasonable degree of medical probability that the cause of Ms. Thompson-Key' s pain, mesh erosion, and dyspareunia is related to her TVT Mesh Implant. This is related to what Dr. Elliott described as a chronic inflammation around the mesh causing a banding or contraction of the sling causing an urethral erosion. As per Dr. Klinge opinion there may be safer alternatives to Gynecare's polypropylene (i.e. laser cut technology (less fraying) or different materials (PVDF). Ethicon's is designed to cause a greater than necessary inflammation and foreign body reaction as is occurring in Ms. Thompson-Key.

XXI.

I have the right to supplement and amend this opinion should additional factual information be forwarded to me that I did not have available at the time this opinion is submitted.

Dated this the 22th day of May, 2017

William Porter, M.D.